1029339

Science For A Better Life

October 24, 2016

U.S. Environmental Protection Agency

Document Processing Desk - 6(a)(2)

Office of Pesticide Programs - 7504P

Room S-4900, One Potomac Yard

Arlington, VA 22202-4501

SUBJECT: 6(a)(2) Incidents Accumulated for Month of September, 2016

Dear Sir/Madam:

Please find additional Bayer Animal Health Division 6(a)(2) incidents accumulated during the month of September, 2016. These incidents are being submitted in accordance with FIFRA Section 6(a)(2).

Bayer
Animal Health

P.O. Box 390
Shawnee Mission, KS
66201-0390

Please feel free to contact me at chris.ensley@bayer.com or 913-268-2730, if I can provide any additional information, or to be any further assistance.

Respectfully,

BAYER

ANIMAL HEALTH DIVISION

Chris Ensley

Chris Ensley

Regulatory Affairs Specialist

Encl: Bayer report nos:

2016-US0055734, 2016-US0055834, 2016-US0055959, 2016-US0056609, 2016-US0056800, 2016-US0057739, 2016-US0057765, 2016-US0058172, 2016-US0058929, 2016-US0059298, 2016-US0059506, 2016-US0059917, 2016-US0061022, 2016-US0061715, 2016-US0061721, 2016-US0061751, 2016-US0062393, 2016-US0062395

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name: Ex. 6 Personal Privacy (PP)	Submission date: 10-24-2016	Contact person (if different than reporter): Not Applicable	Internal ID #: 2016-US0055734
	Address: Ex. 6 Personal Privacy (PP) USA		Address: USA -001	
	Phone #: Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New. If update,include date of original submission	Location and date of incident: 09-02-2016	Date registrant became aware of incident: 09-02-2016	Was incident part of larger study ?: No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1): 11556-152	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s): Imidacloprid-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name: Advantage II Large Cat	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation: Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed?: Yes. Intentional misuse: No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product): (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO?: No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 2		

Version : 7-Sep-2016 at 10:43

Internal ID # 2016-US0055734

Brief description of incident circumstances

On 02-Sep-2016, a 56 year old woman, in unknown condition, with concomitant medical conditions of type II diabetes and hypertension, was exposed to an unknown amount of Advantage II Large Cat (Imidacloprid-Pyriproxyfen) when some of the product got into her mouth and onto her lips after the cat shook 30 minutes after application.

Immediately post exposure, the woman experienced a taste of bitterness. The woman drank water.

The woman was not examined by a physician and the sign continued.

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Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 56 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Minutes *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Taste disorder		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
2016-US0055734

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* approximate

Version : 7-Sep-2016 at 10:43

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name: Ex. 6 Personal Privacy (PP)	Submission date: 10-24-2016	Contact person (if different than reporter): Not Applicable	Internal ID #: 2016-US0055834
	Address: Ex. 6 Personal Privacy (PP)		Address: USA -002	
	Phone #: Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New. If update,include date of original submission	Location and date of incident: 09-02-2016	Date registrant became aware of incident: 09-02-2016	Was incident part of larger study ?: No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1): 11556-130	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s): Imidacloprid-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name: Advantage II Extra Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation: Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed?: Yes. Intentional misuse: No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO?: No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 5		

Version : 7-Sep-2016 at 11:33

Internal ID # 2016-US0055834

Brief description of incident circumstances

On 02-Sep-2016, a woman, in unknown condition, with concomitant medical conditions of hypothyroidism and a memory disorder, who was taking an unspecified thyroid medication orally since approximately 2016, was exposed to an unknown amount of Advantage II Extra Large Dog (Imidacloprid-Pyriproxyfen) when she opened the box and the tubes leaked onto her hands, then she touched her tongue.

Approximately 30 minutes post exposure, the woman experienced a numbness and tingling sensation on the right side of her throat. The woman rinsed her hands.

The woman was not examined by a physician and the signs continued.

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Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 20-64 Years Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 30 Minutes *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Laryngeal irritation Hypoaesthesia		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

2016-US0055834

* approximate

Version : 7-Sep-2016 at 11:33

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Ex. 6 Personal Privacy (PP)	Submission date. 10-24-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0055959
	Address Ex. 6 Personal Privacy (PP)		Address USA - 005	
	Phone # Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-05-2016	Date registrant became aware of incident. 09-05-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-144	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Imidacloprid-Permethrin-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name K9 Advantix II Extra Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 8		

Version : 8-Sep-2016 at 10:17

Internal ID # 2016-US0055959

Brief description of incident circumstances

On 05-Sep-2016, a 57 year old woman, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of K9 Advantix II Extra Large Dog (Imidacloprid-Permethrin-Pyriproxyfen) when she bit the tube to open it and a small amount squirted into her mouth.

Approximately 5 minutes post exposure, the woman experienced a slight tingling sensation on her tongue. The woman rinsed her mouth and the sign continued.

The woman was not examined by a physician.

Demographic information: Age: 57 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 5 Minutes *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Paraesthesia		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
2016-US0055959 10

* approximate

Version : 8-Sep-2016 at 10:17

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Ex. 6 Personal Privacy (PP)	10-24-2016	Not Applicable	2016-US0056609

Address	Address
Ex. 6 Personal Privacy (PP)	USA -004

Phone #	Phone #
Ex. 6 Personal Privacy (PP)	

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	09-07-2016	09-07-2016	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
11556-152		
A.I. (s)	**A.I. (s)**	**A.I. (s)**
Imidacloprid-Pyriproxyfen		
Product 1 name	**Product 2 name**	**Product 3 name**
Advantage II Large Cat		
Exposed to concentrate prior to dilution ?	**Exposed to concentrate prior to dilution ?**	**Exposed to concentrate prior to dilution ?**
Formulation	**Formulation**	**Formulation**
Topical solution		

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Yes Intentional misuse No		See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : 9-Sep-2016 at 08:23

Internal ID # 2016-US0056609

Brief description of incident circumstances

On 07-Sep-2016, a 57 year old, woman, in unknown condition, with concomitant medical conditions of diabetes, hypertension, depression and bipolar disorder, who was taking an unspecified blood pressure medication, an unspecified anti-depressant medication, an unspecified bipolar medication, unspecified vitamins and an unspecified baby aspirin since approximately 2016, was exposed to an unknown amount of Advantage II Large Cat (Imidacloprid-Pyriproxyfen) when she applied the product to her cat and placed the cap from the tube in her mouth to hold it.

Immediately post exposure, the woman experienced a taste of the product (bad taste). The woman rinsed her mouth with water and wiped her tongue with a towel. Approximately 5 minutes post exposure, the woman experienced a tingling sensation on the side of her tongue.

The woman was not examined by a physician and the signs continued.

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Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 57 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Minutes *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Taste disorder Paraesthesia		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

2016-US0056609 13

* approximate

Version : 9-Sep-2016 at 08:23

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name: Ex. 6 Personal Privacy (PP)	Submission date: 10-24-2016	Contact person (if different than reporter): Not Applicable	Internal ID #: 2016-US0056800
	Address: Ex. 6 Personal Privacy (PP)		Address: USA -005	
	Phone #: Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New. If update,include date of original submission	Location and date of incident: 08-30-2016	Date registrant became aware of incident: 09-07-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1): Unknown	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s): Imidacloprid-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name: Advantage II (dog-unspecified)	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation: Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes. Intentional misuse: No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 14		

Version : 9-Sep-2016 at 07:54

Internal ID # 2016-US0056800

Brief description of incident circumstances

On 30-Aug-2016, a 79 year old, woman, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of Advantage II (dog-unspecified) (Imidacloprid-Pyriproxyfen) when she applied it to her dog and rubbed the product in with her hands.

Immediately post exposure, the woman washed her hands with an unspecified soap.

Approximately 2 hours post exposure, the woman experienced an application site rash, application site pruritus, and application site pain on her hands.

On 07-Sep-216, the rash spread to the woman's arms and feet and was pruritic. The woman was examined by a physician who treated the woman with an unknown dose of prednisone orally.

The signs continued.

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Demographic information: Age: 79 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 2 Hours *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Dilute/irrigate/wash	List signs/symptoms/adverse effects Application site inflammation Application site pruritus Application site pain Dermatitis and eczema		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
2016-US0056800 16

* approximate

Version : 9-Sep-2016 at 07:54

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name: Ex. 6 Personal Privacy (PP)	Submission date: 10-24-2016	Contact person (if different than reporter): Not Applicable	Internal ID #: 2016-US0057739
	Ex. 6 Personal Privacy (PP)		Address: USA	
	Phone #: Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New. If update, include date of original submission	Location and date of incident: 09-11-2016	Date registrant became aware of incident: 09-11-2016	Was incident part of larger study ?: No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1): 11556-143	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s): Imidacloprid-Permethrin-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name: K9 Advantix II Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation: Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed?: Yes. Intentional misuse: No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO?: No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances		

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Version : 13-Sep-2016 at 09:21

Internal ID # 2016-US0057739

Brief description of incident circumstances

On 11-Sep-2016, a woman, in unknown condition, with concomitant seasonal allergies, was exposed to an unknown amount of K9 Advantix II Large Dog (Imidacloprid-Permethrin-Pyriproxyfen) when she rubbed her eye after she petted the dog who had the product applied on 08-Sep-2016.

Approximately 1 hour post exposure, the woman experienced a burning sensation to the skin around her eyes.

The woman was not examined by a physician and the sign continued.

Demographic information: Age: 20-64 Years Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Hours *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Paraesthesia		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
2016-US0057739 19

* approximate

Version : 13-Sep-2016 at 09:21

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name: Ex. 6 Personal Privacy (PP)	Submission date: 10-24-2016	Contact person (if different than reporter): Not Applicable	Internal ID #: 2016-US0057765
	Address: Ex. 6 Personal Privacy (PP)		Address: USA -007	
	Phone #: Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New. If update,include date of original submission	Location and date of incident: 09-11-2016	Date registrant became aware of incident: 09-11-2016	Was incident part of larger study ?: No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1): 11556-125	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s): Imidacloprid-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name: Advantage II Medium Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation: Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed?: Yes. Intentional misuse: No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO?: No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 20		

Version : 13-Sep-2016 at 09:53

Internal ID # 2016-US0057765

Brief description of incident circumstances

On 11-Sep-2016, a 23 year old, man, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of Advantage II Medium Dog (Imidacloprid-Pyriproxyfen) when he put his mouth on the application site of the dog who had the product applied approximately 3 hours earlier on the same day.

Immediately post exposure, the man experienced tongue numbness. The man immediately rinsed his mouth with water and approximately 2 hours post onset, the sign resolved without medical intervention.

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Demographic information: Age: 23 Year(s) Sex : Male Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Minutes *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Hypoaesthesia		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
2016-US0057765 22

* approximate

Version : 13-Sep-2016 at 09:53

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name: Ex. 6 Personal Privacy (PP)	Submission date: 10-24-2016	Contact person (if different than reporter): Not Provided	Internal ID #: 2016-US0058172
	Address: Ex. 6 Personal Privacy (PP)		Address: USA -008	
	Phone #: Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New. If update,include date of original submission	Location and date of incident: 09-02-2016	Date registrant became aware of incident: 09-12-2016	Was incident part of larger study ?: No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1): 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s): Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name: Seresto Dog (unspecified)	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation: Collar	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed?: Yes. Intentional misuse: No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO?: No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 23		

Version : 16-Sep-2016 at 10:51

Internal ID # 2016-US0058172

Brief description of incident circumstances

On 31-Aug-2016, a 58 year old, man, in unknown condition, with a concomitant medical condition of an unspecified back disorder, was exposed to 1 Seresto Dog (unspecified) (Flumethrin-Imidacloprid) collar when he applied it around the neck of his dog. The man washes his hands every time he pets the dog.

On 02-Sep-2016, the man had symptoms of lip, mouth, and tongue numbness, loss of taste, anorexia, sore throat with difficulty swallowing and weight loss of 16 pounds.

On 03-Sep-2016, the man was examined by a doctor, tested negative for strep throat, and started on a regimen of amoxicillin by mouth.

On an unknown date in Sep2016, the collar was removed from the dog for several days before reapplication occurred. The symptoms continued during this time frame.

As of 12-Sep-2016, the symptoms localized to his throat are improved. The other signs continued and no further medical intervention has been sought.

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Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 58 Year(s) Sex : Male Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 2 Days	

Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects	If lab tests were performed, list test names and results(If available submit report).
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown	Hypoaesthesia Taste disorder Anorexia Laryngeal irritation Dysphagia Weight loss	None reported
Human severity category H-C		

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

2016-US0058172 25

Version : 16-Sep-2016 at 10:51

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Ex. 6 Personal Privacy (PP)	10-24-2016	Not Applicable	2016-US0058929

Address	Address
Ex. 6 Personal Privacy (PP)	USA -009

Phone #	Phone #
Ex. 6 Personal Privacy (PP)	

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	09-14-2016	09-14-2016	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
11556-152		
A.I. (s)	**A.I. (s)**	**A.I. (s)**
Imidacloprid-Pyriproxyfen		
Product 1 name	**Product 2 name**	**Product 3 name**
Advantage II Large Cat		
Exposed to concentrate prior to dilution ?	**Exposed to concentrate prior to dilution ?**	**Exposed to concentrate prior to dilution ?**
Formulation	**Formulation**	**Formulation**
Topical solution		

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Yes Intentional misuse No		See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 26	

Version : 19-Sep-2016 at 11:00

Internal ID # 2016-US0058929

Brief description of incident circumstances

On 14-Sep-2016, a 55 year old, woman, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown volume of Advantage II Large Cat (Imidacloprid-Pyriproxyfen) when applying the product to her cat. The woman squeezed a small amount of the product on a piece of paper and then placed her cigarette lighter on the same piece of paper. There was no known direct product exposure to the woman or the lighter. The woman then lit a cigarette and ate a cookie.

Approximately 5 minutes post exposure, the woman experienced symptoms of jaw pain, upset stomach, heartburn, and light headedness.

Approximately 10 minutes post onset, the jaw pain resolved. No medical intervention was sought and the symptoms continued.

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Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 55 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 5 Minutes *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Jaw disorder Dyspepsia Dysphagia Dizziness		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

2016-US0058929

28

* approximate

Version : 19-Sep-2016 at 11:00

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Ex. 6 Personal Privacy (PP)	Submission date. 10-24-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0059298
	Address Ex. 6 Personal Privacy (PP)		Address USA	
	Phone # Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-04-2016	Date registrant became aware of incident. 09-15-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name Seresto Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Collar	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 29		

Version : 19-Sep-2016 at 08:40

Internal ID # 2016-US0059298

Brief description of incident circumstances

On an unspecified date in Jun-2016, a woman, in unknown condition, with no known concomitant medical conditions, was accidentally exposed to an unknown amount of 1 Seresto Large Dog (Flumethrin-Imidacloprid) collar on her hands when she applied it to her dog.

On approximately 04-Aug-2016, the woman experienced a dry cough daily.

On an unspecified date post onset of sign, in 2016, the woman was examined by a physician who performed a thoracic radiograph which was normal. No known treatments was performed.

On 26-Aug-2016, the woman removed the collar from the dog and bathed the dog with a liquid dish soap. No further medical intervention was sought and the woman continued to have a dry cough.

30

Demographic information: Age: Unknown Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: Unknown	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Cough		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category M-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
2016-US0059298 31

Version : 19-Sep-2016 at 08:40

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name: Ex. 6 Personal Privacy (PP)	Submission date: 10-24-2016	Contact person (if different than reporter): not applicable	Internal ID #: 2016-US0059506
	Address: Ex. 6 Personal Privacy (PP)		Address: USA -011	
	Phone #: Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New. If update,include date of original submission	Location and date of incident: 09-15-2016	Date registrant became aware of incident: 09-16-2016	Was incident part of larger study ?: No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1): 11556-152	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s): Imidacloprid-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name: Advantage II Large Cat	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation: Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed?: Yes. Intentional misuse: No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).: See Incident Description Notes	
	Applicator certified PCO?: No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).: See Incident Description	Brief description of incident circumstances: 32		

Version : 20-Sep-2016 at 12:31

Internal ID # 2016-US0059506

Brief description of incident circumstances

On 15Sep2016, a 28 year old woman, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of Advantage II Large Cat (Imidacloprid-Pyriproxyfen) when the product got onto her tongue while she opened the tube with her mouth.

Immediately post product exposure, the woman developed a numbing sensation on the tip of her tongue.

On 16Sep2016, the symptom continued unchanged and the woman was not evaluated by a physician.

33

Demographic information: Age: 28 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Minutes *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) No therapy, observation	List signs/symptoms/adverse effects Hypoaesthesia		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
2016-US0059506 34

* approximate

Version : 20-Sep-2016 at 12:31

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Ex. 6 Personal Privacy (PP)	Submission date. 10-24-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0059917
	Address Ex. 6 Personal Privacy (PP)		Address USA -012	
	Phone # Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-16-2016	Date registrant became aware of incident. 09-19-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name Seresto Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Collar	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 35		

Version : 21-Sep-2016 at 14:42

Internal ID # 2016-US0059917

Brief description of incident circumstances

On 16-Sep-2016, a 55 year old, woman, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of 1 Seresto Large Dog (Flumethrin-Imidacloprid) collar when she applied it to her dog.

At an unspecified time on approximately 16-Sep-2016, post application, the woman experienced generalized hives. The woman washed with an unspecified soap and applied an unspecified lidocaine ointment topically.

On approximately 17-Sep-2016, the woman experienced small, red, skin ulcerations at the exposure site.

On 18-Sep-2016, the woman experienced bleeding from the exposure site, which resolved at an unspecified time on the same day.

On 19-Sep-2016, the woman experienced shiny, skin lesions at the exposure site.

The woman was not examined by a physician and the signs continued.

36

Demographic information: Age: 55 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: Unknown	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Urticaria Application site erythema Application site ulcer Application site haemorrhage Application site lesion		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
2016-US0059917 37

Version : 21-Sep-2016 at 14:42

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name: Ex. 6 Personal Privacy (PP)	Submission date: 10-24-2016	Contact person (if different than reporter): Not Applicable	Internal ID #: 2016-US0061022
	Address: Ex. 6 Personal Privacy (PP)		Address: USA -013	
	Phone #: Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New. If update,include date of original submission	Location and date of incident: 09-07-2016	Date registrant became aware of incident: 09-22-2016	Was incident part of larger study ?: No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1): 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s): Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name: Seresto Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation: Collar	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed?: Yes. Intentional misuse: No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating): See Incident Description Notes	
	Applicator certified PCO?: No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff): See Incident Description	Brief description of incident circumstances: 38		

Version : 26-Sep-2016 at 10:30

Internal ID # 2016-US0061022

Brief description of incident circumstances

On 06-Sep-2016, a 73 year old, woman, in unknown condition, with concomitant medical conditions of skin allergies and multiple sclerosis, who was administered an unspecified multiple sclerosis medication, cyanocobalamin injections, duloxetine orally, aripiprazole via an unknown route, and an unspecified vitamin all since an unknown date in 2016, was exposed to an unknown amount of 1 Seresto Large Dog (Flumethrin-Imidacloprid) collar on her hands when she placed it around her dog's neck.

On approximately 07-Sep-2016, the woman experienced facial swelling, periorbital swelling, lip swelling, a rash, and felt weak. The individual was transported via an ambulance to an emergency room and was examined by an emergency room physician and was treated with unspecified intravenous fluids, intravenous diphenhydramine and oxygen. The physician performed unspecified blood work and a cat scan with the results unknown. The woman was discharged from the emergency room and experienced exhaustion.

On approximately 15-Sep-2016, the woman was exposed on her hands to an unknown amount of the Seresto Large Dog collar when she removed the collar from the dog and approximately 1 hour post exposure, she experienced pruritus and edema at the exposure site on her hands. The individual washed her hands with an unspecified soap and the pruritus and edema at the exposure site of her hands resolved within approximately 12 hours. All other clinical signs continued.

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Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 73 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Days *	

Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects	If lab tests were performed, list test names and results(If available submit report).
Diphenhydramine;Fluids,	Allergic oedema Periorbital oedema Allergic oedema Dermatitis and eczema Lethargy Lethargy Application site pruritus Application site oedema	None reported

Exposure data:
Amount of pesticide:
Unknown per 1

Expose duration:
9 Days
Patient weight:
Unknown

Human severity category
H-C

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
2016-US0061022
40

* approximate

Version : 26-Sep-2016 at 10:30

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Ex. 6 Personal Privacy (PP)	Submission date. 10-24-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0061715
	Address Ex. 6 Personal Privacy (PP)		Address USA -014	
	Phone # Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-23-2016	Date registrant became aware of incident. 09-26-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-142	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Imidacloprid-Permethrin-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name K9 Advantix II Medium Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 41		

Version : 28-Sep-2016 at 11:56

Internal ID # 2016-US0061715

Brief description of incident circumstances

On 22-Sep-2016, a 67 year old, woman, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of K9 Advantix II Medium Dog (Imidacloprid-Permethrin-Pyriproxyfen) when she applied it to her dog. No known direct exposure occurred.

On 23-Sep-2016, the individual experienced erythema and blisters on an unspecified arm.

On approximately 25-Sep-2016, the individual was examined by a physician and treated with an unspecified ointment topically.

On approximately 26-Sep-2016, the signs worsened.

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Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 67 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Days	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Dilute/irrigate/wash;Unkno	List signs/symptoms/adverse effects Erythema Bullous disorder		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
2016-US0061715 43

Version : 28-Sep-2016 at 11:56

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Ex. 6 Personal Privacy (PP)	Submission date. 10-24-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0061721
	Address Ex. 6 Personal Privacy (PP)		Address USA -015	
	Phone # Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-26-2016	Date registrant became aware of incident. 09-26-2016	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-144	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) Imidacloprid-Permethrin-Pyriproxyfen	A.I. (s)	A.I. (s)
	Product 1 name K9 Advantix II Extra Large Dog	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation Topical solution	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 44	

Version : 28-Sep-2016 at 13:34

Internal ID # 2016-US0061721

Brief description of incident circumstances

On 25-Sep-2016, a 31 year old, woman, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of K9 Advantix II Extra Large Dog (Imidacloprid-Permethrin-Pyriproxyfen) when she applied it to her dog who tried to run and she got some on her hands.

Approximately 1 hour post exposure, the individual washed her hands with an unspecified soap.

On 26-Sep-2016, the individual experienced light headedness, dizziness, nausea, sweating, and disorientation. The individual self administered an unknown dose of acetaminophen orally and drank water.

The individual was not examined by a physician and the signs continued.

45

Demographic information: Age: 31 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Days	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Dizziness Dizziness Nausea Hyperhidrosis Mental confusion		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID # 46
2016-US0061721

Version : 28-Sep-2016 at 13:34

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name: Ex. 6 Personal Privacy (PP)	Submission date: 10-24-2016	Contact person (if different than reporter): Not Applicable	Internal ID #: 2016-US0061751
	Address: Ex. 6 Personal Privacy (PP)		Address: USA -016	
	Phone #: Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New. If update,include date of original submission	Location and date of incident: 09-01-2016	Date registrant became aware of incident: 09-27-2016	Was incident part of larger study ?: No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1): Unknown	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s): Imidacloprid-Permethrin-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name: K9 Advantix II (unspecified)	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation: Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed?: Yes. Intentional misuse: No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO?: No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 47		

Version : 30-Sep-2016 at 14:52

Internal ID # 2016-US0061751

Brief description of incident circumstances

On an unspecified date in Sep 2016, a 1 year boy, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of K9 Advantix II (unspecified) (Imidacloprid-Permethrin-Pyriproxyfen) when he played with dogs to which the product had been applied the same day. No known direct exposure occurred.

Four days after playing with the dogs in Sep 2016, the boy developed urticaria and pimples on his arms, face, and behind his ears.

On 28Sep2016, the symptoms were improving. He was not evaluated by a physician.

48

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 1 Year(s) - Sex : Male Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 4 Days	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Urticaria Dermatitis and eczema		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
2016-US0061751

49

Version : 30-Sep-2016 at 14:52

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name: Ex. 6 Personal Privacy (PP)	Submission date: 10-24-2016	Contact person (if different than reporter): Not Applicable	Internal ID #: 2016-US0062393
	Address: Ex. 6 Personal Privacy (PP)		Address: USA -017	
	Phone #: Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New. If update, include date of original submission	Location and date of incident: 09-28-2016	Date registrant became aware of incident: 09-28-2016	Was incident part of larger study ?: No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1): 11556-144	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s): Imidacloprid-Permethrin-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name: K9 Advantix II Extra Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation: Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed?: Yes. Intentional misuse: No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO?: No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 50		

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Internal ID # 2016-US0062393

Brief description of incident circumstances

On 27-Sep-2016, an 8 year old boy, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of K9 Advantix II Extra Large Dog (Imidacloprid-Permethrin-Pyriproxyfen) when it was applied to the dog and the dog slept with him.

On 28-Sep-2016, the individual experienced a burning sensation on his face. The individual's face was washed with an unspecified soap, then the individual experienced erythema on his face.

The individual was not examined by a physician and the signs continued.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 8 Year(s) Sex : Male Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Days	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Paraesthesia Erythema		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name: Ex. 6 Personal Privacy (PP)	Submission date: 10-24-2016	Contact person (if different than reporter): Not Applicable	Internal ID #: 2016-US0062395
	Address: Ex. 6 Personal Privacy (PP)		Address: USA -018	
	Phone #: Ex. 6 Personal Privacy (PP)		Phone #	
	Incident Status: New. If update, include date of original submission	Location and date of incident: 01-01-2016	Date registrant became aware of incident: 09-28-2016	Was incident part of larger study ?: No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1): 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s): Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name: Seresto Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation: Collar	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed?: Yes. Intentional misuse: No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO?: No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 53		

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Internal ID # 2016-US0062395

Brief description of incident circumstances

On 28-Aug-2016, an approximately 82 year old, woman, in unknown condition, with concomitant medical conditions of suspected seasonal allergies, was exposed to an unknown amount of 1 Seresto Large Dog (Flumethrin-Imidacloprid) collar when it was applied to her dog. It is unknown if any direct exposure occurred.

On an unspecified date post exposure, the individual experienced erythema and irritation to an unspecified elbow. The individual was examined by a physician who treated with an unspecified halobetasol cream topically.

The signs continued.

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Demographic information: Age: 82 Year(s) - * Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: Unknown	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Steroids, Topical	List signs/symptoms/adverse effects Erythema Pruritus		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

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* approximate

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